

REMARKS/ARGUMENTS

Applicant respectfully requests entry of this amendment and reconsideration of this application.

Claims 2-6, 8, 9 and 11-46 are pending herein. Claims 2, 32, 3344 and 46 have been amended. No new matter has been introduced as a result of the claim amendments. By the amendments, Applicant does not acquiesce to the propriety of any of the Office's rejections and does not disclaim any subject matter to which Applicant is entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

Rejections under 35 USC §112

1. Claims 8 and 9 have been rejected under 35 USC §112, first paragraph as failing to comply with the written description requirement. The Office states that "there is insufficient support in the disclosure for the limiting the inner diameter of the pores to be greater than about 1 μ m."

In the specification paragraph 0096 ample support is provided for this limitation. More specifically, paragraph 0096 states that the pores can have a diameter between less than about 1 μ m up to about 10 μ m.

2. Claims 29-33 have been rejected under 35 USC §112, first paragraph as failing to comply with the written description requirement. The Office states that there is insufficient support for a fourth material located between the first material and the third material. Ample support for this is found for example in figure 3 and paragraph 00100.

More specifically, and by way of example, substrate 52 is a third material, tie layer 54 is a fourth material, porous composite coating layer 56 is the first material and discrete composite particles make up the second composite material. Tie layer 54 is disposed between the first material (56) and the third material (substrate 52).

3. Claims 29-33 have been rejected under 35 USC §112, first paragraph as failing to comply with the enablement requirement. This appears to be an erroneous

rejection. The confusion appears to come from the Office's statement that claim 29 depends from claim 17. In Applicants last response however, claim 29 was amended to depend from claim 2 rather than claim 17.

4. Claims 2-11 and 16-43 have been rejected under 35 USC §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which application regards as the invention. In item 8, paragraph 1, the Office is unclear as to what Applicant is intending to claim and refers the reader to a particular quoted limitation.

What Applicant is intending to claim, *inter alia*, is a plurality of discrete particles each comprising a bioerodible material and a bioactive agent. The disclosure supports codeposition of these particles with a first material onto the stent. Therefore, the discrete particles define, in part, the pores with the pores surrounding, in part, the discrete particles.

In item 8, paragraph 2, the Office also erroneously states that claim 29 depends from claim 17. As stated above, claim 29 has been previously amended to change its dependency to claim 2.

Claim 2 is further rejected because "said plurality of discrete particles" in line 8 lacks antecedent basis. See office action item 9. Claim 2 has been amended to address this item.

Claim 32 is also rejected because the limitation "the first coating material" lacks antecedent basis. See office action item 10. Claims 32 and 33 have been amended to address this item.

In light of the foregoing, Applicants respectfully request the withdrawal of the rejections under 35 USC §112

Rejections under 35 USC §102/103

Claims 2-6, 12-31, 34-37, 39 and 43-46 have been rejected under 35 USC §102(e) as allegedly being anticipated by, or in the alternative, as obvious over O'Brien et al. (US 2005/0060021) ("O'Brien").

Amended Claim 2 now requires, in combination with an endolumenal stent with a porous surface comprising a first material and having a plurality of pores:

- (a) a second composite material that is different than the first material and that comprises a plurality of discrete particles comprising a bioerodible material in combination with a bioactive agent; and
- (b) the plurality of discrete particles are structurally co-deposited together with said first material on said endolumenal surface and within each of the pores that are formed at least in part around the particles and thereby comprising a co-deposited composite surface coating, such that the pores having an inner diameter in the vicinity of the particles that is substantially equivalent to an outer diameter of the particles.

A party asserting that a patent claim is anticipated under 35 USC 102 must demonstrate among other things, "identity of invention." *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983). Anticipation under Section 102 can be found only if a reference shows exactly what is claimed. *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985). For a prior art reference to anticipate in terms of 35 USC 102, every element of the claimed invention must be identically shown in a single reference. *In re Bond*, 910 F.2d 831, (Fed. Cir. 1990).

O'Brien does not show, teach or suggest each and every element of the rejected claims as presently presented.

The Office Action alleges that O'Brien discloses a stent (figure 2A) comprising a scaffold from a third material (20/60), an intermediate fourth material (22/62), a porous surface (24/64) comprising a first coating material (26) having a plurality of discrete pores (27, 28) and a second composite material comprising a plurality of particles wherein each particle may be defined as a small portion of the second material located within each of the pores, or the volume of the second material entirely filling each pore. The second material is composed of a bioactive agent in combination with a bioerodable polymer material. See Office Action item 12.

Contrary to the allegation in the Office Action that a plurality of particles is disclosed in O'Brien, Applicant cannot find such a disclosure anywhere in O'Brien. O'Brien does not disclose a plurality of discrete particles, much less particles constructed of composite material comprising bioerodible polymer in combination with a bioactive agent, much less such composite particles in a structurally co-deposited composite surface coating.

The Office characterizes element 26 of O'Brien as a first coating with a plurality of discrete pores. This is simply a mischaracterization of O'Brien's explicit teachings. O'Brien forms hollow tube shaped elements by anodization. These tube shaped elements are simply not discrete pores, nor can they be characterized as a porous material. The tubes 26 define voids 27 and 28. The material 26 itself is not porous nor are there a plurality of discrete particles within the material 26. Material 26 defines voids and provides wells or depots for therapeutic material. There are no discrete composite particles as claimed by Applicant nor are there any such particles in the material 26 itself.

Moreover, the Office states that the particle diameter may be defined by the inner diameter of the tubes of O'Brien. These tubes do not, however, define discrete particles. Rather, a therapeutic agent fills the tubes.

Furthermore, O'Brien's structure does not meet the claimed limitation of "structurally codeposited." O'Brien's tubes are formed by anodization and subsequently post loaded with a therapeutic agent. Contrary, Applicant's limitation of "structurally codeposit" results in composite discrete particles that are applied to the surface with the first material such that a structure where the first material forms, at least in part, around the particles. Therefore, the particles are, at least in part, defining the porous structure. O'Brien is not "porous." It discloses hollow tubes. O'Brien does not show composite discrete particles defining the porosity.

Regarding independent claim 12, it is not clear in the explanation portion of the Office Action for this ground for rejection where or how O'Brien was intended to be applied against Claim 12, as while it was included summarily under the ground for

rejection it was not addressed directly in the body of the section, nor were its required limitations directly addressed or compared against allegedly anticipatory or obvious disclosure in O'Brien.

Reference numerals 64 and 24 of O'Brien define hollow tubes created, for example, via an anodization process. The material itself does not contain a plurality of pores. Rather, they define hollow tubes and or circumscribe voids which can be loaded with therapeutic material.

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the Office's rejection of claims 2-6, 12-31, 34-37, 39 and 43-46 under 35 USC §102 or 103.

35 U.S.C. §103 Rejections

1. Claims 8 and 9 have been rejected under 35 USC §103(a) as being unpatentable over O'Brien et al. as applied to claim 2.

Claims 8 and 9 depend from claim 2. O'Brien does not teach or suggest each and every element of the rejected claims as presently presented, as discussed *supra*. Lye does not cure the deficiencies of O'Brien. Therefore, Applicant respectfully requests the withdrawal of the rejection on this basis.

2. Claim 11 has been rejected under 35 USC §103(a) as being unpatentable over O'Brien et al. as applied to claim 2, in view of Lye et al. (US 2004/0148015) ("Lye").

Claim 11 depends from claim 2. O'Brien does not teach or suggest each and every element of the rejected claims as presently presented, as discussed *supra*. Lye does not cure the deficiencies of O'Brien. Therefore, Applicant respectfully requests the withdrawal of the rejection on this basis.

3. Claims 32 and 33 have been rejected under 35 USC §103(a) as allegedly being unpatentable over by O'Brien et al. in view of Gertner et al. (US 2003/0060873) ("Gertner").

Claims 32 and 33 depend from claim 2. O'Brien does not teach or suggest each and every element of the rejected claims as presently presented, as discussed *supra*. Gertner does not cure the deficiencies of O'Brien. Therefore, Applicant respectfully requests the withdrawal of the rejection on this basis.

4. Claim 38 has been rejected under 35 USC §103(a) as being unpatentable over O'Brien et al. as applied to claim 2, in view of Wang et al. (US 2007/0037739) ("Wang").

Claim 38 depends from claim 2. O'Brien does not teach or suggest each and every element of the rejected claims as presently presented, as discussed *supra*. Wang does not cure the deficiencies of O'Brien. Therefore, Applicant respectfully requests the withdrawal of the rejection on this basis.

5. Claims 40-42 have been rejected under 35 USC §103(a) as being unpatentable over O'Brien et al. as applied to claim 2.

Claims 40-42 depend from claim 2. O'Brien does not teach or suggest each and every element of the rejected claims as presently presented, as discussed *supra*. Therefore, Applicant respectfully requests the withdrawal of the rejection on this basis.

CONCLUSION

Applicant has amended the present claims in order to clarify certain aspects previously presented prior to the present amendment, and which distinguish over the cited references alleged to provide grounds for rejection in the recent Office Action. All amendments made have been for clarity, and find abundant support in the present Application as originally filed, and no new matter has been added nor should any new search be required by this Amendment. The present amendments have been made in good faith in order to provide clarity to the originally intended subject matter of the claims prior to this amendment to expedite the application toward positive allowance. However, these amendments have been made without prejudice, estoppel, or dedication to the public of the original scope of the claims, as originally filed or otherwise in their intervening form prior to this Amendment, and reserves the right to

pursue that subject matter prior to this amendment for future prosecution, such as for example via continuation practice.

Applicant has also provided remarks to accompany the present amendment, which include request for reconsideration and withdrawal of all grounds for rejection in the Office Action. All grounds for rejection being adequately addressed and traversed, Applicant respectfully requests that a Notice of Allowance be issued and that the present Application please be passed to issuance.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-3207.

Respectfully submitted,

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